To Prospective Clinical Mentors,

Thank you for your interest in the Undergraduate BME Design Team Program! If you are interested in harnessing the collective skill, energy, and talent of our design teams, please submit your design challenge for our next round of projects. If selected, a team of 5-8 undergraduate biomedical engineering students plus faculty will work with you and a group of medtech design and commercialization experts over the course of a year to develop solutions to your design challenge!

Our Process:

Our program has been designed to emulate the new product development process commonly found in industry. Over the course of the academic year, students are instructed on customer discovery, concept development and assessment, regulatory strategy, IP strategy, prototyping, and functional testing. By the end of the academic year, students will have validated their clinical need with extensive literature and stakeholder analysis, generated and prioritized multiple design concepts, and developed and tested a functional prototype that addresses their clinical need.

The rigor and quality of our program have been demonstrated year after year in the success of our student teams. In the last decade, our program has achieved:

> 900 students trained
>40 provisional patents
>16 start-up companies founded
>$2M in funding
>100 awards in competitions

Clinician Mentor Benefits:

The Design Team program provides clinicians with a unique opportunity to collaborate with biomedical engineers in the innovation process. Working with a design team provides clinicians access to a network of resources including a team of dedicated students, engineering and innovation faculty, experts in intellectual property, regulatory affairs and commercialization. Our students are some of the brightest minds that our university has to offer, and they do an excellent job of defining and distilling projects into tangible results.

Please contact us with any questions @ elizabeth.logsdon@gmail.com or @ nickdurr@gmail.com . We would love to hear from you!

What to Expect:

After submission, our Design Team faculty will reach out to sponsors to discuss the project and the sponsor's goals to help align interests and expectations for the year. Sponsors are invited to attend pitch nights in-person or through video conference to pitch their projects to the student teams in mid-march, and to meet with teams to discuss the project as the students vet and prioritize projects. Projects are then matched to teams based on interest by May 10th and an introductory meeting between the team, the sponsor, and DT faculty is held to set summer goals. While the timeline and outcomes vary from project to project, the average team working on a project of moderate complexity generally aligns with the timeline below:

	Phase 1: Identify & Define	**Phase 2: Ideate and Evaluate**
FALL	**August - October 15th** Students will focus on identifying the root problems associated with the presented challenge and will perform an in-depth analysis of relevant disease-states, epidemiology, and clinical workflows associated with the challenge.	**October 15th - December** Students will shore up any unresolved components from Phase 1 and will focus on the conceptualization and preliminary assessment of solution ideas to select a top concept to move forward with in prototyping and testing
	Phase 3: Iterate and Test	**Phase 4: Verify and Validate**
SPRING	**January - March 15th** Students will conduct multiple rounds of prototyping and evaluation to refine their concept into a functional design	**March 15th - May** Students will perform more thorough testing on a refined prototype of their device in order to assess at least one key functionality/usability requirement of the solution.

Successful projects typically:

- involve accessible sponsors that can devote an average of 1 hour per week to working with the student team,
- benefit from resources like experimental equipment, IRB support, and animal models,
- give student teams access to clinical staff, colleagues, residents, and nurses,
- fit within an appropriate scope for one year of undergraduate work,
- involve a technical solution and a design component,
- and treat design team students as collaborative partners with some degree of independence.

Please contact us with any questions @ elizabeth.logsdon@gmail.com or @ nickdurr@gmail.com . We would love to hear from you!

Expectations / Commitments of Team Members:
A successful Design Team project requires the alignment and commitment of the mentors, faculty, and students. Each member has their own responsibilities to ensure that the project moves forward.

Mentor Responsibilities:

- Meet with interested student teams in late February/March to work through the submitted challenge and answer any student questions regarding the challenge.
- Commit to at least one meeting with student team or team leader during the summer.
- Commit to at least 1 hour/week of interaction with the team through in-person, online, or phone meetings in the Fall and Spring semesters.
- Commit to at least three in-person (or online) committee meetings lasting approximately 1.5 hours each (one in the fall, two in the spring).

Faculty Responsibilities:

- Instruct the students on biodesign principles through lectures, workshops, and guest speakers
- Support team leaders in the management of team activities
- Host biweekly meetings with the entire team to review research progress, solution assessment, and testing progress.
- Host biweekly meetings with individual team members to gauge team cohesivity, project status, and team member concerns.
- Assist the teams in finding suitable subject-matter experts to give research/clinical/design advice and to join the team's advisory committee
- Liaise as necessary between student team and committee members to resolve any concerns/disputes
- Grade team members based on their completion of course-specific assignments and deliverables.

Student Team Responsibilities:

- Complete all course deliverables as specified in the Design Team Guidelines
- Compile and maintain an electronic design history file (DHF) that records the research, development, and testing of any solutions.
- Meet at least once a month with the project sponsor to provide an update on project progress
- Commit approximately 10 hours per week per team member towards furthering the project and/or associated deliverables.

Please contact us with any questions @ elizabeth.logsdon@gmail.com or @ nickdurr@gmail.com . We would love to hear from you!

Intellectual Property:

The student teams are encouraged to include their sponsors in the ideation process in order to foster equal investment in the project and to strengthen the overall quality of potential solutions. However, inventorship and rights to IP are subject to their legal definitions and larger policies.

Any inventors that are faculty, staff, or graduate students that are supported by Johns Hopkins University are subject to the Johns Hopkins Policy on Intellectual Property

Please contact us with any questions @ elizabeth.logsdon@gmail.com or @ nickdurr@gmail.com . We would love to hear from you!

Memorandum of Understanding (MOU) on Expectations from Students, Clinicians, and other Partners Working on JHU BME Design Teams

We, the undersigned, agree to work together on a Johns Hopkins BME Design Team. This team is focused on the development of an innovative healthcare solution in the following area starting in Fall 20XX academic year:

_____ (AREA)

The team will consist of the undersigned JHU students (5 in the fall, 8 in the spring) and the project Mentor, in addition to the BME faculty. The team will be advised by the BME faculty and an assembled advisory committee. The team will be provided access by BME to additional resources and external experts, such as legal experts, investors, regulatory experts, and technical experts, who have offered to provide advice to the team. This is a 2 course sequence for the primary student team (5 students). It follows the design thinking process leading the team through 4 phases:

> **Phase 1. Fall:** Identify and Define
> **Phase 2. Fall:** Ideate and Evaluate
> **Phase 3. Spring:** Iterate and Test
> **Phase 4. Spring:** Verify and Validate

The first semester is dedicated to obtaining a deep understanding of the problem and constraints for the solution concept and its development. The spring semester is dedicated to rapid iteration through solution concept testing and early validation of the solution with stakeholders. Major deliverables include generation and maintenance of a Design History File , a manuscript draft (journal selected by the team and mentor), a video pitch and electronic poster.

**If you have any questions please contact the DT course directors,
Nicholas Durr (ndurr@jhu.edu) and Elizabeth Logsdon (elogsdo1@jhu.edu).**

We commit to the following in the course of this team work:

1. Engage each other actively in all stages of the project, including: identification, definition, validation and refinement of the clinical need, brainstorming on potential solutions, technical development, verification and validation testing, assessment of business, regulatory, reimbursement and other topics.

2. Clinical, student and other team members agree to spend sufficient time on the project to perform the obligations above, including regular face-to-face meetings, conference calls, online meetings and emails. Clinicians agree to spend at least one hour every two weeks for these obligations.

3. Work together in the writing of any grants, papers, posters and other material related to the AREA during the course of this project. This includes informing and making reasonable effort to gain approval from all team members before any such materials are presented outside of the BME program.

4. Clinician team members agree to assist student team members with access to operating procedures, other clinical activity, and feedback needed for the success of the project, in a manner consistent with JHMI rules on exposure of students to clinical care.

5. By mutual consent of team members, new team members may be added to the project.

6. Regarding IP:
a) If agreed, collectively develop, prepare, and file with JHTV disclosures or independent agencies on all intellectual property developed in the course of the duration of this project in the AREA. At the time of such filing, work together and in consultation with course faculty, and JHTV or other agencies to clarify and agree upon inventorship and the fair share of contributions of each inventor on a disclosure.
OR
b) For outside sponsored project refer to other IP agreements.

7. In the case where a team member brings to the project pre-existing intellectual property (IP), clinical data, or other significant resources, that team member will document such contributions before the start of the project and these will be recognized by the other team members. Documentation of any prior IP by JHU employees should be done according to JHU IP guidelines.

8. Undergraduate students in design team do not have an obligation to assign intellectual property to JHU if they are working on an unsponsored project. However, they may choose to work with JHU Tech Ventures and use their resources if they agree to assign to JHU.

9. For unsponsored projects, if all the inventors on an invention do not have an obligation to assign their intellectual property to an organization, they may choose to file their own IP outside JHU. For sponsored projects, the sponsor and the team must discuss and understand the IP obligations of each team member before starting work together.

10. I have been given the "JHU Intellectual Property Policy" (link here: https://ventures.jhu.edu/the-johns-hopkins-ip-policy/) and understand that if I have any questions about my rights or obligations under the University policy, I will see to have them answered before I assign any IP rights to JHU.

All mentors as asked to sign an MOU prior to the start of the project.

I agree to make good faith efforts to fulfill my commitments outlined in this memorandum of understanding.

Agreed and Signed (Please print name, sign, and date)

_____
Signature   /   Date

_____
Student Team Member (print name)

_____
Signature   /   Date

_____
Student Team Member (print name)

_____
Signature   /   Date

_____
Student Team Member (print name)

_____
Signature   /   Date

_____
Student Team Member (print name)

_____
Signature   /   Date

_____
Student Team Member (print name)

_____
Signature   /   Date

_____
Project Mentor (print name)

_____
Signature   /   Date

_____
Project Mentor (print name)

_____
Signature   /   Date

_____
Design Team Faculty (print name)